

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No. : 10/669,978
Confirmation No. : 9246
Applicant(s) : THOMAS HAAS, ET AL.
Filed : SEPTEMBER 24, 2003
TC/A.U. : 1754
Examiner : Wayne A. Langel
Title : AQUEOUS HYDROGEN PEROXIDE SOLUTIONS AND METHOD
OF MAKING SAME

Docket No. : 032301.309
Customer No. : 25461

Commissioner for Patents
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APPELLANTS' REPLY BRIEF UNDER 37 C.F.R. § 41.41

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Now come Appellants and reply to the Examiner's Answer dated November 17, 2006, as follows:

An amendment under 37 C.F.R. § 41.33(b)(2) was filed January 10, 2007 for the purpose of rewriting Claims 16-18 in independent form, thereby placing them in condition for allowance.

On page 4, first paragraph, of the Examiner's Answer, it is contended that because *Tsao* '689 is silent as to the presence or absence of alkali metals and alkaline earth metals, the compositions shown in *Tsao* '689 would inherently contain less than 50 wppm alkali metals or alkaline earth metals.

As understood, the position expressed in the Examiner's Answer is that the *Tsao* reference inherently discloses compositions coming within the scope of the claims on appeal. The position expressed in the Examiner's Answer appears to be based, in part, on the disclosure in the *Tsao* '689 patent, at col. 2, lines 48-58, that the amine content may be as low as 0.003 wt.% (30 ppm) and that anions, such as ammonium, comprise at least 100 wppm.

In response, appellants point out that the amounts specified in the *Tsao* '689 reference with respect to stabilizers, such as diethylene triamine penta(methylenephosphonic acid), relate to the weight of the total composition and not to the weight of hydrogen peroxide as is required by Claim 1. *Tsao* '689 teaches that the solutions of his invention contain 0.5 to about 6% by weight of hydrogen peroxide; see col. 2, lines 51-52 and lines 63-64. Taking into consideration the extremely high dilution of the hydrogen peroxide solution having a hydrogen peroxide content of 0.5 to 6 wt.%, the stated lower limit for the diethylene triamine penta(methylenephosphonic acid) stabilizer of 0.003% is calculated as 0.05% of the stabilizer

additive based on the weight of hydrogen peroxide when the concentration of hydrogen peroxide is 6%. That is $0.003 \div 0.06 = 0.05\%$. The value of 0.05% converts to 500 ppm based on the weight of hydrogen peroxide and not 30 ppm as stated in the Examiner's Answer on page 4, lines 4-5.

The position taken in the Examiner's Answer appears to be due to the assumption that the amounts of components, such as stabilizers, added to the hydrogen peroxide solution refer to the absolute amount of these ingredients in the final hydrogen peroxide solution.

This interpretation of the *Tsao* disclosure is, in appellants' view, not justified. Appellants invite attention to col. 2, lines 30 to 39, of *Tsao* where the reference explicitly teaches "employing diethylene triamine penta(methylenephosphinic acid) or a physiologically compatible salt thereof, as a stabilizer". Appellants submit the whole disclosure of the *Tsao* reference can only be interpreted in the sense that these amounts of stabilizers disclosed refer to the stabilizer added to an already existing hydrogen peroxide solution. In other words, the amounts of stabilizer are based on the total solution, not just the hydrogen peroxide present. The Examiner's interpretation, thus, would only be correct in case the *Tsao* reference used a hydrogen peroxide solution totally free of any impurities. But a person skilled in the art knows that in the world of chemistry, there is hardly a product that is totally free of impurities.

The Official Action expresses the reasons in support of the rejection as being based on inherency in the prior art reference. An allegation that a certain result or characteristic may occur or be present in the prior art is not a sufficient basis to establish the inherency of that particular result or characteristic. To establish inherency, the evidence of record must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.

In relying upon the theory of inherency, the burden is upon the examiners to provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Appellants take the position that the official record has not established that *Tsao* necessarily and inevitably discloses compositions falling within the scope of the claims in the present application.

The Examiner's Answer refers to the disclosure in the *Tsao* '689 reference, in col. 3, lines 51-68, that there "may" be present in the stabilized hydrogen peroxide solution one or more tonicity enhancing agents. See Examiner's Answer, pg. 4, at bottom. Based on that statement, the Examiner's Answer says that this shows that the tonicity enhancing agents (e.g., alkali metals) can be absent. But it does not establish that such agents are necessarily absent.

The Examiner's Answer then alleges that the presence of the stabilizer in the composition of the *Tsao* '689 reference would provide at least 100 wppm anions or compounds that can dissociate to form anions while still providing less than 50 wppm alkali metals. See pg. 5, last paragraph.

Again, attention is invited to col. 2, lines 30-39 of the *Tsao* reference where explicitly is disclosed that "diethylene triamine penta(methylenephosphonic acid) or a physiologically compatible salt thereof" can be employed as a stabilizer. This means that those amounts of stabilizers are added to an already existing hydrogen peroxide solution.

The Examiner's position appears to be that the amounts of additional components added to the hydrogen peroxide solution refer to an absolute amount of these ingredients in the final hydrogen peroxide solution and appear to assume that the hydrogen peroxide solution would be totally free of any impurities. However, the disclosure in the *Tsao* reference shows that nothing more than a commercially available hydrogen peroxide material was used which, as is generally

known, would not be totally free of impurities. Indeed, in col. 2, lines 4-7, *Tsao* refers to impurities.

Consequently, from the amounts disclosed in the *Tsao* reference of additives to be added to a hydrogen peroxide solution, no conclusion can be drawn with respect to the actual total amount of alkali or alkaline earth metals in the final solution. If in fact a totally pure hydrogen peroxide was intended by the reference, it would have been expressly disclosed. In fact, the evidence is to the contrary, see col. 2, lines 4-7.

On pg. 6 of the Examiner's Answer, first full paragraph, the allegation is made that appellants have not provided any evidence that would support the conclusion that the commercial hydrogen peroxide solution contains "high amounts of alkali metal ions and/or amines".

Of record in this application is the International Publication WO 00/76989 on pg. 13 of which there is a table showing the amount of phosphate, nitrate and sodium ions for commercial hydrogen peroxide solutions. In this table the amounts are given based on the total weight of the solution, whereas in the present claim the amount of, for example, alkali metal ions is based on the total weight of hydrogen peroxide.

Listed below is a table showing the sodium ion content based on weight of solution in accordance with Table 1 on page 13 of the WO 00/76989, as well as the sodium ion content based on the weight of hydrogen peroxide using the concentration given for the commercial hydrogen peroxide solution in the table in the prior art.

Commercially Available Hydrogen Peroxide Solution	Sodium Ion Content Based on Weight of Solution	Sodium Ion Content Based on the Weight of Hydrogen Peroxide
A	30 ppm	100 ppm
B	23 ppm	58 ppm
C	50 ppm	167 ppm

D	60 ppm	120 ppm
E	11 ppm	37 ppm
F	19 ppm	38 ppm
G	20 ppm	100 ppm

It will be evident from the last column in this table that of the seven commercial hydrogen peroxide solutions, five of them have a sodium content that is above the 50 ppm limit of the total amount of alkali metals and alkaline earth metals defined in Claim 1.

The *Tsao* reference does not specify the composition of the original hydrogen peroxide solution to which stabilizers are added. Appellants submit there is insufficient evidence of record to show that the hydrogen peroxide solution has a content of alkali or alkaline earth metals below the limits defined in the present application.

Appellants respectfully submit it cannot be concluded that the *Tsao* reference necessarily and inherently discloses a composition falling within the scope of the present invention. Therefore, the rejection citing 35 U.S.C. § 102(b) and based on a theory of inherency is flawed.

Furthermore, there is nothing in the *Tsao* reference which discloses any steps taken to obtain a hydrogen peroxide solution that is substantially free of or below the upper limits of the alkali metal/alkaline earth metal contents as defined in Claim 1. Nothing in *Tsao* provides any teaching, suggestion or motivation which would be a reason for the skilled worker to create a composition having the parameters defined in Claim 1.

It is further contended in the Examiner's Answer that a person skilled in the art would have been lead to use a hydrogen peroxide solution having the required low content of alkali/alkaline earth metals.

However, there is nothing in the *Tsao* reference which would suggest that alkali metals, particularly sodium, or alkaline earth metals would be detrimental for the desired use intended by

the reference. On the contrary, the sodium salts of the stabilizers are most preferred and in order to obtain an isotonic solution, it is even preferred to add sodium chloride, see col. 4, example 1.

In summary, a person skilled in the art would have no reason to create a highly purified hydrogen peroxide solution which is obviously more expensive than the commercially available hydrogen peroxide solution as a starting composition for the sole purpose of reducing the amount of alkali metals. The clear teaching of *Tsao* is that the alkali metals are not detrimental for the purposes of the reference and, on the contrary, are the preferred embodiments of the invention.

Therefore, appellants submit that the Examiner's Answer fails to establish anticipation because of the lack of inherency and fails to provide any teaching, suggestion, or motivation whereby a person skilled in the art would have any reason to change or modify the compositions shown in the *Tsao* reference.

For the reasons set forth above, as well as in the main Brief, appellants respectfully request reversal of the final rejection.

Respectfully submitted,

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